REMARKS

Claim Amendments

Two claims did not have a period at their end. Correction is made.

New claims are also added.

Rejections Under 35 U.S.C. § 112

Claims 12, 14, 33, 35 and 48 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled.

The Office Action holds applicants to a standard of enablement that is contrary to well established law.

In a proper enablement rejection, which is not made here, first and foremost, a specification disclosure which "contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." (Emphasis added.) *In re Marzocchi*, supra. "The PTO must have adequate support for its challenge to the credibility of appellant's statements of utility". (The quoted statement was made in the context of enablement, i.e., the how-to-use requirement of the first paragraph of section 112.) See also *In re Bundy*, 642 F.2d 430, 209 USPQ 48, (CCPA 1981). The only relevant concern of the Patent Office should be over the truth of assertions relating to enablement. The first paragraph of section 112 requires nothing more than objective enablement. See *In re Marzocchi, supra.*

The Examiner has not established any basis to doubt objective enablement. The Examiner has also provided no support for establishing that one of ordinary skill would doubt the objective truth of the asserted utility, which is enabled by the specification. The enablement rejections by the Examiner are thus unfounded. The rejection therefore was improper under *In re Marzocchi.*

The claims rejected are directed to a method of fertility control, a method of inhibiting the initiation of implantation of a conceptus, a method of inhibiting the maintenance of implantation of a conceptus, i.e., to treatments and activities that are not objectively doubtable. Doubt has been held reasonable only where, for example, the invention has been characterized as "highly unusual," *In re Houghton*, 433 F.2d 820 (CCPA 1970), as

"incredible," *In re Citron*, 325 F.2d 248, (CCPA 1963), or as "too speculative," *In re Eltgroth*, 419 F.2d 918 (CCPA 1970). Because compounds/compositions having similar therapeutic activities are known in the art, the existence of a new class of compounds/compositions having the claimed activities is not objectively doubtable, i.e., not "highly unusual," "incredible," and/or "too speculative."

Without proper reason or evidence to doubt the objective truth of the enabling disclosure, the Examiner improperly requires evidence to prove utility and/or to support enablement. "Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility." *See In re Bundy*, supra. The burden has not been shifted. Thus, appellants are not required to provide rebuttal evidence.

With regard to *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), the Office Action merely lists the eight factors set out therein, but makes no factual allegations. Merely reciting the factors from Wands does not amount to a proper rejection.

Even if reliance is placed on these factors, or on some of these factors, by the Office Action, which is not clear, Wands also states that no factor alone is determinative, and that the "test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed."

Applicants provided adequate guidance in the specification for one of ordinary skill in the art as to how to proceed in using the claimed invention. Pages 8 (last paragraph) and 11 (last paragraph) of the specification provide lists of antiprogestins. Additionally, one of ordinary skill in this art either readily knows numerous antiprogestins by structure or can determine by routine testing whether a given compound has an antiprogestin activity or not. There are standard assays for this activity. The specification combined with the knowledge of the skilled artisan provides sufficient guidance for one skilled in the art to practice the invention without undue experimentation. Thus, the claims are enabled.

The Office Action cites *General Electric Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 37 USPQ 466 (CAFC 1938), and quotes language about the impropriety of the use of functional language at the point of novelty. The issue raised by the quoted language was specifically discussed in *In re Swinehart*, 169 USPQ 226 (CCPA 1971), which states that

> any concern over the use of functional language at the so-called "point of novelty" stems largely from the fear that an applicant will attempt to distinguish over a reference disclosure by emphasizing a property or function which may not be mentioned by the reference and thereby assert that his claimed subject matter is novel. Such a concern is not only irrelevant, it is misplaced. ... We are convinced that there is no support, either in the actual holdings of prior cases or in the statute, for the proposition, put forward here, that "functional" language, in and of itself, renders a claim improper.

The Office Action also cites *University of California v. Eli Lilly and Co.*, 43 USPQ 1398 (CAFC 1997) and alleges that this decision discusses the use of functional language and that it states that such usage does "little more than outlin [e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate." However, this language is taken out of context. First, this language relates to written description issues, which is not the rejection made here. Thus, this language is irrelevant to enablement. Second, the court states in the same paragraph as the language quoted by the Examiner that "in claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function." Thus, the quoted language addresses specific issues related to a claim to genetic material, and not to functional language as used in the present claims. Third, *Eli Lilly* involves the claiming of genes by function, where there was no way for one of ordinary skill in the art to determine the structure of the gene based on the recited function at the time the application was filed. The present case is different. As noted above, one of ordinary skill in this art either readily knows numerous antiprogestins by structure or can determine by routine testing whether a given compound has an antiprogestin activity or not.

Additionally, even though the cited language is not relevant to the present rejection, the holding of the same was clarified by the CAFC, which stated that "*Eli Lilly* did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure." See *Moba v. Diamond Automation*, 66 USPQ2d 1429 (CAFC 2003) discussing *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). As said above, ordinary artisans in this field readily know numerous antiprogestins by structure or can determine whether a given compound possesses such activity by routine testing. Thus, even if the language quoted by the Examiner would apply to the present case,

such has to be viewed in light of the clarification by the CAFC discussed above, in which case, the rejection cannot be maintained on the present facts.

The Office Action also alleges that "to envision compounds recited functionally, the skilled artisan must be provided great numbers of compounds residing in those compound classes envisioned thereby providing guidance as to those compounds suitable to practice the invention as claimed."

As mentioned earlier, the specification provides two lists of antiprogestins. Why this is not sufficient is not explained.

Additionally, the requirement made by the Examiner has no basis in patent law. Instead, the law is clear that "it may not be necessary to enumerate a plurality of species if a genus is sufficiently identified in an application by 'other appropriate language.'" See *In re Grimme*, 124 USPQ 499 (CCPA 1960). Additionally, "mention of representative compounds encompassed by generic claim language clearly is not required by Section 112 or any other provision of the statute." See *In re Robins*, 429 F.2d 452, 166 USPQ 552 (CCPA 1970). Thus, neither case-law nor stature requires what the Office Action requires of applicants, i.e., the enumeration of "great numbers of compounds." The description of the genus antiprogestins and the enumaration of species in two lists as discussed above is sufficient to enable the use of antiprogestins, especially in view of what is known by those of skill in this art.

Additionally, applicants request an explanation of what number of compounds would satisfy the "great numbers of compounds" requirement.

The Office Action also alleges that "the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity." This requirement also has no basis.

With respect to pharmaceutical inventions, the specific issue whether an applicant is required to test the claimed compounds in their use has been answered. The Federal Circuit in *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), stated that

> usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful can be well before it is ready to be administered to humans. If the courts were to require Phase II testing in order to prove utility for pharmaceutical inventions, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Additionally, *In re Angstadt*, 537 F.2d at 502-03, 190 USPQ 214 (CCPA 1976) provides that an applicant is "*not* required to disclose *every* species encompassed by their claims even in an unpredictable art." Thus, not only does an applicant not have to test each of the compounds, but even in an unpredictable art, every species is not required to be disclosed. *Utter v Higara*, 845 F.2d at 998-99, 6 USPQ2d 1714 (CAFC 1988) also holds that a specification may, within the meaning of Section 112 Para. 1, enable a broadly claimed invention without describing all species that the claim encompasses.

In the pharmaceutical arts, it is adequate that the specification disclose the activity of the compounds of the invention without testing them. In *Bundy*, supra, the specification therein provided no examples and disclosed only that the compounds of the invention possess activity similar to E-type prostaglandins. Nevertheless the court found that sufficient guidelines as to use were given in the disclosure. The court held that "what is necessary to satisfy the how-to-use requirement of section 112 is the disclosure of some activity coupled with knowledge as to the use of this activity." (Emphasis added.) Appellants have done at least that in the present case and more, and thus, satisfied the how-to-use requirement of section 112.

Reconsideration is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 12-14, 33-35 and 48 have been rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Garfield et al. and Teutsch et al..

Garfield et al. relates to inhibiting ovulation by administering a nitric oxide synthase inhibitor alone or in combination with one or more of a progestin, an estrogen, and a luteinizing hormone-releasing hormone. Teutsch et al. relates to steroids and compositions thereof, one of which has anti-implantation activity. These two references teach different compounds that operate via different mechanisms. Thus, there is no motivation to combine these compounds to achieve the claimed methods. The cited references, singly or in combination, do not suggest that one could successfully combine a nitric oxide synthase inhibitor and an antiprogestin to control fertility. Thus, the claims are not obvious.

Nevertheless, unexpected results are demonstrated in the attached declaration. The declaration provides a variety of tests and discusses the same in detail. One of ordinary skill in the art based on the disclosure of the prior art would not have expected the demonstrated synergistic effect, i.e., the unexpectedly significantly improved performance of the

combination of a nitric oxide synthase inhibitor with an antiprogestin versus their use independently of each other.

Reconsideration is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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